REMARKS/ARGUMENTS

Claims 4-6, 10, 15, 19, 32, 39, 40, 45, 49, 52-54 and 57-64 are pending in this application. Only claims 54 and 57 are under examination and these claims are both rejected. The remaining claims, i.e., nos. 4-6, 10, 15, 19, 32, 39, 40, 45, 49, 52, 53 and 58-64 are withdrawn by the Examiner from further consideration in this application as being directed to a non-elected invention.

In response to the Office Action applicants have amended claims 54 and 57 and added proposed new claim 65. New claim 65 is substantially identical to claim 54 as amended, with the exception that, instead of reciting a "subpolycythemic dosage" of at least one of erythropoietin or Aranesp (as in claim 54), the new claim provides numerical ranges for the dosages of the erythropoietin and Aranesp. The claim amendments and new claim are supported by the originally filed application and thus they do not raise any issue of new matter. Their entry into the file of the application is, therefore, respectfully solicited. Upon such entry claims 4-6, 10, 15, 19, 32, 39, 40, 45, 49, 52-54 and 57-65 will be pending with claims 54, 57 as amended and new claim 65 being under examination.

Reconsideration of the application is respectfully requested.

Claim Rejections Under 35 U.S.C. §112

At p. 3 the Action states that claims 54 and 57 remain rejected under 35 U.S.C. §112, first paragraph. According to the Office Action at pp. 3-4, the present specification does not enable, "at least one of erythropoietin and a derivative thereof" and "by at least one of prevention of the damage to kidney tissue and regeneration of damaged kidney tissue". Further on p. 3, however, the Action goes on to state that the specification **is enabling** for, "erythropoietin or Aranesp" and "by at least one of diminution or slowing of the damage to kidney tissue".

Applicants respectfully submit that they do not agree with the Examiner's position re: enablement for the reasons presented in their "Amendment Under 37 C.F.R. §1.114" filed August 4, 2010. Nevertheless, notwithstanding their prior arguments but in order to advance the progress of this application, claim 54 is herein amended in response to the "enablement" rejection in the manner proposed by the Examiner, i.e., wherein the amended claim recites that the pharmaceutical composition comprises a subpolycythemic dosage of "erythropoietin or Aranesp" and that the acute or chronic renal failure is treated in the patient "by at least one of

diminution or slowing of the damage to kidney tissue". These amendments are believed to be sufficient for overcoming the rejection. The amendment to claim 57 was made to take into account the above-described amendment to claim 54.

Furthermore, new claim 65 as written contains the same language as described above as being contained in claim 54. Applicants therefore believe that the new claim meets all of the requirements for enablement under 35 U.S.C. 112, first paragraph, taking into account the matters discussed above with regard to amended claim 54.

The Examiner is therefore requested to reconsider and withdraw the rejection of claims 54 and 57 under 35 U.S.C. §112, first paragraph.

Further to the above at p. 19 of the Action the Examiner raises a new claim rejection directed to claims 54 and 57 based on 35 U.S.C. §112, second paragraph. In particular, the Examiner objects to the inclusion of the limitation "prevention", i.e., of the damage to kidney tissue. The rejection is respectfully traversed.

In response, both amended claim 54 and new claim 65 recite that the treatment of the human or animal patient involves, "diminution or slowing of the damage to kidney tissue." Neither claim, in its present form, includes the term "prevention" and, thus, the Examiner is respectfully requested to also reconsider and withdraw the rejection of claims 54 and 57 under 35 U.S.C. §112, second paragraph.

Claim Rejections Under 35 U.S.C. §103

At p. 6 the Office Action states that claims 54 and 57 remain rejected under 35 U.S.C. §103 over Jungers et al. in view of Stehouwer et al. The rejection is respectfully traversed.

Applicants have considered the Examiner's remarks at pp. 7-19 of the Office Action in support of the rejection. However, with due respect to the Examiner, for the reasons provided in the following discussion the rejection is deemed by applicants to lack an appropriate basis. The rejection, therefore, should be withdrawn.

Applicants' traverse of the §103 rejection is based, as indicated in their previous response filed on August 4, 2010, on the fact that, in their view, Jungers et al. very clearly relates to the treatment of anemia, which treatment is shown in the reference to lead to a considerable increase in the hemoglobin (Hb) value – see, for example, p. 309 table 2 of the reference. This is in clear contrast to the presently claimed method that explicitly aims to avoid any increase in the

hematocrit value (see, e.g., pp. 43-48 of the application specification). That is, the indicated portion of the specification clearly teaches one having ordinary skill in this art that the doses used in the presently claimed method do not lead to an increase in the hematocrit.

The Examiner argues that pursuant to how the terms are defined in the present application, the dosage ranges given in Jungers et al. are subpolycythemic doses. More particularly, the Examiner has taken the position that the dose of 54.3 units/kg per week of EPO disclosed in Jungers would fall within the definition of a subpolycythemic dose as that term is defined in applicants' specification. Applicants respectfully disagree with the Examiner's stated position for the reasons that follow.

Pages 44-45 and 46-47 of applicants' specification clearly teach that the 'definition' of a subpolycythemic dose is a dose that does not lead to an increase in a subject's hematocrit. In particular, as taught by applicants, such a dose does not lead to an increase of more than 10%, especially 5% and preferably no more than 2% in the hematocrit when compared to the hematocrit prior to the treatment with EPO. This is clearly distinguishable from the teaching contained in tables 1 and 2 of the Jungers et al. reference (compare the Hb value in the EPO + group in table 1 to the Hb value for the EPO + group at the end of the experiment in table 2).

Therefore, in accordance with the definition provided in the present application the dosage taught in Junkers et al. is not a subpolycythemic dose due to the fact that it raises the hematocrit value of a subject to whom it is administered. The numerical values given in the present application (1 to 90 IU/kg of body weight per week) merely span the potential relevant dosage area in which a dose, specifically designed to take into account the body's physiology, the severity of the disorder, and renal function, may (or, however, might not) be subpolycythemic. That is, a specific dose "x" (e.g., 60 IU/kg body weight per week) falling within the range of 1 to 90 IU/kg body weight per week taught in applicants' specification may, under particular circumstances in a particular patient, function as a subpolycythemic dose, whereas, in a different patient and/or under different conditions such a dose may not be a subpolycythemic dose but would instead be a polycythemic dose. In this regard the Examiner's attention is respectfully directed to pp. 44/46 of the present specification that teaches that the actual dosages are chosen according to the severity of the disorder and depending on the renal function but wherein, in any event, the dosage administered must be a subpolycythemic dose.

The final arbiter is, thus, not the specific amount of the dose but, rather, the fact that the dose does not raise the subject's hematocrit.

In sum, therefore, applicants' specification teaches to one having ordinary skill in this field of art that the claimed method involves the use of a subpolycythemic dosage, i.e., one that does not raise the hematocrit value, which dosage can readily be determined by a skilled artisan upon taking into account the particular patient and their particular pathological status. Thus, as indicated above the criticality in determining whether a dosage is subpolycythemic lies not in maintaining a dosage of between 1-90 IU/kg body weight per week (which may encompass dosages that are polycythemic as well as dosages that are subpolycythemic), but rather in the administration of a dosage that does not raise the subject's hematocrit when taking into account the particular patient and their particular condition.

Taking the above explanation into account, applicants respectfully submit that their claimed method is clearly distinguishable over the combination of Jungers et al. and Stehouwer et al. That is, the basis for distinguishing over Jungers et al. is set forth above while, as noted at p. 15 of applicants' previous response dated August 4, 2010, Stehouwer et al. does not remedy the deficiencies of the primary reference. The Stehouwer et al. reference is cited due to its teaching that microalbuminuria, hypertension, endothelial dysfunction and an increased risk of left ventricular hypertrophy are aspects in CRF patients; however, the reference in no way discloses or even suggests that the claimed subpolycythemic dosage of erythropoietin or Aranesp is capable of achieving the beneficial effects recited in, e.g., claim 54. Thus the combination of the two references neither teaches nor suggests the claimed method.

For all of the reasons given above, therefore, the Examiner is respectfully requested to reconsider and withdraw the rejection under 35 U.S.C. 103 over the combination of Jungers et al. and Stehouwer et al.

Further to the above, moreover, new claim 65 is also believed to be distinguishable over the cited combination. The subject claim does not recite the "subpolycythemic dose" language contained in claim 54; however, it does include a recitation that the dosage ranges from 0.001 to 35 IU/kg of body weight per week of erythropoietin/0.000005 to 0.175 μg/kg of body weight per week of Aranesp (under any circumstances these dosages are sufficiently low that they would inherently constitute a subpolycythemic dosage to a patient). The numerical dosage is nowhere taught or even suggested in either Jungers et al. or Stehouwer et al. and thus the dosage recitation

provides a basis for distinguishing the method recited in new claim 65 over the cited combination. The Examiner, thus, is respectfully requested to allow new claim 65 as well as claims 54 and 57.

Summary

The claim amendments made to claim 54 are believed to place claims 54 and 57 in condition for allowance. New claim 65, moreover, that includes reference to a specific dosage range of EPO/Aranesp as noted above, is also believed to be allowable.

THIS CORRESPONDENCE IS BEING SUBMITTED ELECTRONICALLY THROUGH THE PATENT AND TRADEMARK OFFICE EFS FILING SYSTEM ON February 4, 2011.

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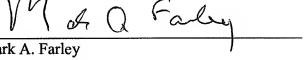
Respectfully submitted,



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